Individual Safety Report

3235249-7-00-01

THE FDA MEDICAL PRODUCTS REPORTER

McNeil Consumer Healthcare

McNeil Consumer Healthcare
Fort Washington, PA 19034-2299

Page ____ of ____

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
APR 0 8 1999
CDR

Approved by FDA on 11/15/93

MFR report #

UF/Distr report #

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
unknown In confidence	1 day or Date of birth: [redacted]	(X) female ( ) male	lbs or .09 kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- (x) death 10/24/94 (mo/day/yr)
- ( ) life-threatening
- (x) hospitalization - initial or prolonged
- ( ) disability
- ( ) congenital anomaly
- ( ) required intervention to prevent permanent impairment/damage
- ( ) other:

3. Date of event: 10/24/94 (mo/day/yr)

4. Date of this report: 04/01/99 (mo/day/yr)

5. Describe event or problem

Medical records from mfr. report #0905668A indicate a STILLBIRTH delivery in a 25-26 week gestation from a mother who took "6 grams/day", 1 gram of unspecified TYLENOL acetaminophen product every 4hrs x 2-3 days PTA. Mother also reported heavy use of cocaine (crack & snorting) first month of pregnancy and use of cocaine 4 days PTA. Mother went to ER on 10/13/94 & was given 2 doses of Tylenol 650 mg. Mother was then admitted to hospital on 10/13/94 with diagnosis of fulminant hepatitis B. On 10/24/94, so sonography confirmed no fetal cardiac motion x5 minutes. Later that day, mother spontaneously delivered stillborn infant girl. An autopsy on infant was performed and the cause of DEATH was listed as an intrauterine fetal demise due to maternal fulminant hepatitis B infection.

6. Relevant tests/laboratory data, including dates

10/13/94 (2000): mother's acetaminophen level=5 (1650 last acetaminophen dose), 10/13/94 mother's drug screen positive for cocaine.

RECEIVED
APR 0 8 1999
BY:

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

9/23/94 mother hepatitis B (+), mother reports heavy use of cocaine during first month of pregnancy

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer/compounder)

#1 TYLENOL Analgesic Unknown

#2

2. Dose, frequency & route used

#1 maternal overdose

#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 2-3 d prior to mother's adm

#2

4. Diagnosis for use (indication)

#1 maternal overdose

#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)

#1 Unknown

#2

7. Exp. date (if known)

#1 Unknown

#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

none

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

DSS
APR 0 9 1999
ADVERSE EVENT REPORTING SYSTEM

2. Phone number: 215-273-7820

3. Report source (check all that apply)

- ( ) foreign
- ( ) study
- ( ) literature
- ( ) consumer
- (x) health professional
- ( ) user facility
- ( ) company representative
- ( ) distributor
- ( ) other:

4. Date received by manufacturer (mo/day/yr): 03/29/99

5. (A) NDA # 19-872
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

- ( ) 5-day (X) 15-day
- ( ) 10-day ( ) periodic
- (X) Initial ( ) follow-up #

8. Adverse event term(s)

STILLBIRTH DEATH

9. Mfr. report number

1152014A

E. Initial reporter

1. Name, address & phone #

[redacted] MD

[redacted]

2. Health professional? (X) Yes ( ) No

3. Occupation: physician

4. Initial reporter also sent report to FDA: ( ) Yes ( ) No (X) Unk

FDA

Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.